



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

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(JW)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/187, 763	11/06/98	ARIMILLI	M 221.P1C

HM12/0510

EXAMINER

AMBROSE, M

ART UNIT	PAPER NUMBER
1613	8

DATE MAILED:

05/10/99

DARYL D MUENCHAU  
GILEAD SCIENCES INC  
333 LAKESIDE DRIVE  
FOSTER CITY CA 94404

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Notice of Allowability</b>	Application No. 09/187,763 Examiner Michael G. Ambrose	Applicant(s) MURTY ARIMILLI, ET AL. Art Unit 1613
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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

1.  This communication is responsive to \_\_\_\_\_.
2.  The allowed claim(s) is/are 35-37; renumbered 1-3, respectively.
3.  The drawings filed on \_\_\_\_\_ are acceptable.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - a)  All    b)  Some\*    c)  None    of the CERTIFIED copies of the priority documents have been
    1.  received.
    2.  received in Application No. (Series Code / Serial Number). \_\_\_\_\_.
    3.  received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

5.  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

A SHORTENED STATUTORY PERIOD FOR REPLY to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office Action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be available under the provisions of 37 CFR 1.136(a).

6.  Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
7.  Applicant MUST submit NEW FORMAL DRAWINGS
  - (a)  because the originally filed drawings were declared by applicant to be informal.
  - (b)  including changes required by the Notice of Draftsperson's Patent Drawing Review( PTO-948) attached
    - 1)  hereto or 2)  to Paper No. \_\_\_\_\_.
  - (c)  including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the examiner.
  - (d)  including changes required by the attached Examiner's Amendment / Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

8.  Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE / SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

#### Attachment(s)

<input type="checkbox"/> Notice of References Cited (PTO-892)	<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	<input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. 5.
<input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. 4.	<input type="checkbox"/> Examiner's Amendment/Comment
<input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	<input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance
	<input type="checkbox"/> Other

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## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 35–37, drawn to (R)-bis(POC)PMPA, a pharmaceutical composition that includes it, and a process for treating a viral infection, classified in class 544, subclass 244, and class 514, subclass 81.
- II. Claim 33, drawn to a process for making 2-(9-purinyl)alkoxymethylphosphonic acid derivatives, classified in class 544, subclass 243 or 244.
- III. Claim 34, drawn to a method of contacting a cell with a phosphonomethoxy nucleotide analog, classified in class 435.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I (i.e., the product of claim 35) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process is disclosed as useful to make a host of 2-(9-purinyl)alkoxymethylphosphonic acid derivatives; it is not limited to preparing (R)-bis(POC)PMPA.

Inventions I (i.e., the product of claim 35) and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

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(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Invention III is drawn to a process that involves the use of a host of 2-(9-purinyl)alkoxymethylphosphonic acid derivatives, not just (R)-bis(POC)PMPA.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Max Hensley on April 20, 1999, a provisional election was made with traverse to prosecute the invention of Group I, claims 35–37. Claims 33 and 34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### *Reasons for Allowance*

The following is an examiner's statement of reasons for allowance: This invention relates to a single embodiment of this invention, namely, (R)-9-(2- bis(propoxycarbonyloxymethyl) phosphonomethoxy)propyladenine, (R)-bis(POC)PMPA, a pharmaceutical composition

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containing it, and a process for treating a person infected with a virus using it. This specific embodiment is within the generic class of compounds claimed in parent application serial no. 08/900,746, which was allowed. A terminal disclaimer has been made of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Telephone and Facsimile Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Ambrose whose telephone number is (703) 308-4529. The examiner can normally be reached Tuesday through Friday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached on (703) 308-4532. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Very respectfully,

Michael G. Ambrose  
**Michael G. Ambrose, Ph.D.**  
Primary Examiner  
Patent Examining Group 1610,  
Art Unit 1613



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

**NOTICE OF ALLOWANCE AND ISSUE FEE DUE**

HM12/0510

DARYL D MUENCHAU  
GILEAD SCIENCES INC  
333 LAKESIDE DRIVE  
FOSTER CITY CA 94404

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/187,763	11/06/98	003	AMBROSE, M	1613 05/10/99
First Named Applicant	ARIMILLI,	35 USC 154(b) term ext. =	0 Days.	

**TITLE OF INVENTION** ANTIVIRAL PHOSPHONOMETHOXY NUCLEOTIDE ANALOGS HAVING INCREASED ORAL BIOAVAILABILITY

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEES DUE	DATE DUE
I 221.P1C	514-081.000	S90	UTILITY	NO	\$1210.00	08/10/99

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.  
PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.

Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

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